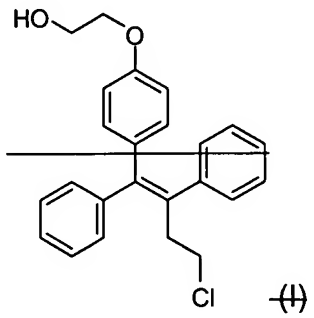
**In the Claims**:

Please amend the Claims as follows (the changes in these Claims are shown with ~~strikethrough~~ for deleted matter and underlines for added matter). A complete listing of the claims proper claim identifiers is set forth below.

1. (**Currently Amended**) A solid drug formulation comprising granulates containing 30 to 90 mg of ospemifene ~~a therapeutically active compound in particulate form said compound having the formula (I)~~




~~(I)~~

~~or a geometric isomer, a stereoisomer,~~ or a pharmaceutically acceptable salt~~, an ester thereof or a metabolite~~ thereof, ~~wherein 90% of the particles have a size less than 50 micrometers and 50% of the particles have a size less than 15 micrometers,~~ in combination with one or more intra-granular excipients, wherein at least one intra-granular excipient is a disintegrant~~, wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method~~.

2. (**Currently Amended**) The drug formulation according to claim 1 wherein ~~compound (I) is~~ the ospemifene is a free base.

3. (**Previously Presented**) The drug formulation according to claim 1 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethyl-cellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

4. (**Original**) The drug formulation according to claim 1 wherein at least one intra-granular excipient is a diluent.

5. (**Original**) The drug formulation according to claim 1 wherein at least one intra-granular excipient is a binder.

6. (**Currently Amended**) The drug formulation according to claim 1 wherein the intra-granular excipient is

~~- a combination of at least one diluent and at least one binder;~~

- a combination of at least one diluent and at least one disintegrant;

- a combination of at least one disintegrant and at least one binder; or

- a combination of at least one diluent, at least one disintegrant and at least one binder.

7. (**Previously Presented**) The drug formulation according to claim 3 wherein the disintegrant is in the range of 0.1 to 10 weight-% of the granulates.

8. (**Original**) The drug formulation according to claim 4 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

9. (**Original**) The drug formulation according to claim 5 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

10. (**Withdrawn**) The drug formulation according to claim 1 wherein the granulates are made by dry granulation.

11. (**Original**) The drug formulation according to claim 1 wherein the granulates are made by wet granulation.

12. (**Withdrawn**) The drug formulation according to claim 1 wherein the formulation is a capsule comprising the granulates encapsulated in a shell.

13. (**Withdrawn**) The drug formulation according to claim 12 wherein the formulation comprises an extra-granular lubricant.

14. (**Withdrawn**) The drug formulation according to claim 13 wherein the lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable oil, poloxamer, a mineral oil, sodium lauryl sulphate, sodium stearyl fumarate, zinc stearate and combinations thereof.

15. (**Withdrawn**) The drug formulation according to claim 1, wherein the formulation is a tablet comprising the granulates in combination with one or more extra-granular excipient.

16. (**Withdrawn**) The drug formulation according to claim 15, wherein the extra-granular excipient is selected from the group consisting of one or more disintegrants, one or more diluents, one or more binders, one or more lubricants, and their combinations.

17. (**Withdrawn**) The drug formulation according to claim 16, where the extra-granular disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

18. (**Withdrawn**) The drug formulation according to claim 16, where the extra-granular diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose,

silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

19. (**Withdrawn**) The drug formulation according to claim 16 wherein the extra-granular binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

20. (**Withdrawn**) The drug formulation according to claim 16 wherein the extra-granular lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable oil, poloxamer, a mineral oil, sodium lauryl sulphate, sodium stearyl fumarate, zinc stearate and combinations thereof.

Claims 21 – 23 (**Canceled**).

24. (**Previously Presented**) The drug formulation according to claim 2 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethyl-cellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

Claims 25 and 26 (**Canceled**).

27. (**Currently Amended**) The drug formulation according to claim 2 wherein the intra-granular excipient is

~~- a combination of at least one diluent and at least one binder;~~

- a combination at least one diluent and at least one disintegrant;

- a combination of at least one disintegrant and at least one binder; or

- a combination of at least one diluent, at least one disintegrant and at least one binder.

28. (**Currently Amended**) The drug formulation according to claim ~~27~~ 24 wherein the disintegrant is in the range of 0.1 to 10 weight-% of the granulates.

29. (**Currently Amended**) The drug formulation according to claim ~~28~~ 27 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

30. (**Previously Presented**) The drug formulation according to claim 29 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

31. (**New**) The drug formulation according to claim 1 wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP paddle method.

32. (**New**) The drug formulation according to claim 28 wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP paddle method.

33. (**New**) A solid drug formulation comprising granulates containing 30 to 90 mg of ospemifene or a pharmaceutically acceptable salt thereof in combination with one or more excipients selected from pregelatinized starch, maize starch, povidone, sodium starch glycolate, and magnesium stearate, wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

34. (**New**) A solid drug formulation according to claim 33 comprising granulates of the following ingredients:

| Names of the ingredients | Quantity (%) GRANULATION | Quantity (%) DIRECT COMPRESSION | Function |
|---|---|---|---|
| Ospemifene | 30 | 30 | Active |
| Pregelatinized starch | 38 | 38 | Diluent |
| Maize starch | 25 | 25 | Diluent |
| Povidone | 2 | 2 | Binder |
| Sodium starch glycolate | 4 | 4 | Disintegrant |
| Magnesium stearate | 1 | 1 | Lubricant |
| Water, purified* | 25 | - | Solvent |

* Evaporates during the manufacturing process

wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

35. (**New**) A method of preparing ospemifene or a pharmaceutically acceptable salt thereof comprising granulating a particulate form of ospemifene or a pharmaceutically acceptable salt thereof wherein 90% of the ospemifene particles have a size less than 50 micrometers and 50% of the particles have a size less than 15 micrometers with one or more intra-granular excipients.

36. (**New**) The method according to claim 35 wherein the granulates are made by wet granulation.

37. (**New**) The method according to claim 36 wherein at least one of the intra-granular excipients is a disintegrant.

38. (**New**) The method according to claim 35 wherein the intra-granular excipient is within the range of 0.1 to 10 weight-% of the granulates.

39. (**New**) The method according to claim 37 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.